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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,138	04/18/2001	John H.J. Petrini	800.019US3	9954

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/837,138	PETRINI ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 5,6,20-22 and 26-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) 20 and 21 is/are allowed.

6)☐ Claim(s) 5,6,22 and 26-28 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/2/04+ 4/18/01.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 5, 6 and 26 have been amended. Claims 16-18 and 23-25 have been canceled. Claim 28 has been added. Claims 5, 6, 20-22 and 26-28 are pending and under consideration.

2. Sections of Title 35 US Code not found in this action can be found in a previous action.

3. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how claim 28 further limits claims 5 or 6 because the limitations of molecular weight of about 95000 Da as determined by SDS-PAGE and vertebrate DNA repair polypeptide are already present in claims 5 and 6.

4. The rejection of claims 5, 6, 22, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for full length DNA repair proteins that bind to Mel1/Rad50, does not reasonably provide enablement for biological fragments thereof having DNA repair activity which bind to Mel1/Rad50 is maintained for reasons of record. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 28 is rejected for the same reasons of record.

Claims 5 and 6 are drawn in part to a method reliant upon a biologically active fragment of a DNA repair polypeptide.

The specification merely contemplates that "biologically active fragments" are part of the claimed invention, not instructions limiting the type of biological activity, guidance with respect to specific protein domains nor have any working examples have been set forth.

The claims are drawn in part to methods of altering the amount of a DNA repair polypeptide in a cell by the expression of an isolated nucleic acid encoding, or antisense to, a biologically active fragment of a DNA repair polypeptide having a molecular weight of about 95 kDa. and which binds the Mrel1/Rad50 complex and which exhibits DNA repair activity It is noted that the specification does not teach a discreet enzymatic function for p95 and the only DNA repair activity which can be attributed to p95 is its presence in the mel1/Rad50 complex.

The art teaches that the function of a single DNA repair protein is complex as it interacts with numerous cellular proteins. The specification teaches that the p95 of the instant invention is part of a complex comprising Mel1 and Rad50: The specification teaches that Nijmegen breakage syndrome patients possess a mutated NBS1 gene and cells taken from said patients exhibit impaired double strand break repair after exposure to ionizing radiation. The prior art (Dolganov et al, Molecular and Cellular biology, 1996, Vol 16, pp. 4832-4841) and the instant specification teach that Mel1 and Rad50 associate with the instant p95 protein and two additional proteins of 200 kD and 350 kD. The specification does not teach a fragment of the p95 protein which could maintain the association with Mel1/Rad50/p200/p350 and it is unreasonable to assume that a fragment of p95 will be able to interact with the other members of the complex. There are no teaching in the specification to indicate that less than the full length of the p95 protein would be sufficient to maintain double strand break repair. The specification fails to teach fragments of the p95 polypeptide which retain a specific "DNA repair activity". Given these lack of teachings and the unreliability of the art with respect to the complexity of interactions between DNA repair polypeptides and other cellular proteins, one of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to make and use the broadly claimed invention.

Applicant argues that it would not be undue experimentation to make and use fragment s of p95. Applicant argues that the screening program to identify fragments of p95 with selected activity is precisely why a program to do so is carried out. This has been considered but not found persuasive. The instant claims are drawn to a method of altering the amount of a DNA repair polypeptide in a cell comprising providing an isolated nucleic acid molecule of p95 o fragments of p95 which bind to double strand breaks in DNA or form a complex with Mrel1/Rad50. This is clearly not a method of screening fragments for double stranded DNA binding activity or the ability to bind to Mrel1/Rad50. For the instant method to be carried out one of skill in the art would need to know which fragments of p95 have said activity, or if indeed there wee any fragments of p95 which could mimic the binding of p95 to Mrel1/Rad50. Thus, it would be undue experimentation, without reasonable expectation of success to practice the broadly claimed invention.

5. Claims 5, 6, 22, 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 5, 6, and 26 have been amended to recite two alternative characteristics for the biologically active fragments, the first being that said fragment are able to bind to double strand breaks in DNA, and the second being that the fragments bind to the Brel1/Rad50 complex. The specification and originally filed claims do not provide support for these limitations with regard to "fragments". Applicant has failed to point out the support for this amendment in the specification,.

6. Claims 20 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
05/16/2004

KAREN A. CANELLA PH.D
PRIMARY EXAMINER